

K090096

182

5. 510(k) SUMMARY

December 12, 2008

OWNER:

JAN 30 2009

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Sr. Manager, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085
Telephone: (847) 270-4871
Fax: (847) 785-5116

DEVICE NAME:

Trade name: All-In-One Container
Name

Table 5-1.
Product Codes for All-In-One Container

| Code number | Size | Name |
|-------------|---------|--|
| 2B8114 | 1000 mL | All-In-One Empty Container, (Three Lead Transfer Set) |
| 2B8124 | 2000 mL | All-In-One Empty Container, (Three Lead Transfer Set) |
| 2B8134 | 3000 mL | All-In-One Empty Container, (Three Lead Transfer Set) |
| 2B8144 | 4000 mL | All-In-One Empty Container, (Three Lead Transfer Set) |
| 2B8112 | 1000 mL | All-In-One Empty Container, (Single Lead Transfer Set) |
| 2B8122 | 2000 mL | All-In-One Empty Container, (Single Lead Transfer Set) |
| 2B8132 | 3000 mL | All-In-One Empty Container, (Single Lead Transfer Set) |
| 2B8142 | 4000 mL | All-In-One Empty Container, (Single Lead Transfer Set) |
| 2B8152 | 500 mL | All-In-One Empty Container, (Single Lead Transfer Set) |
| 2B8172 | 250 mL | All-In-One Empty Container, (Single Lead Transfer Set) |

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Common Name: Compounding Container

Classification Name: Intravenous Container (21 CFR 880.5025, Product Code KPE)

Predicate Device:

**Table 5-2.
Predicate Device**

| Device | Company | Previous 510(k) | Clearance date |
|-------------------------------|-------------------|-----------------|------------------|
| Modified All-In-One Container | Baxter Healthcare | K983294 | November 3, 1998 |

DESCRIPTION OF THE DEVICE:

The All-In-One Container is an empty EVA (Ethylene Vinyl Acetate) container intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

STATEMENT OF INTENDED USE:

The All-In-One Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The All-In-One Container is substantially equivalent to Baxter's current legally marketed All-In-One Container cleared November 3, 1998 (K983294).

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use.

CONCLUSION:

The All-In-One Container is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Baxter Healthcare Corporation
C/o Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

JAN 30 2009

Re: K090096
Trade/Device Name: All-In-One Container
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: January 15, 2009
Received: January 15, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

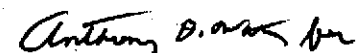
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K090096

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: All-In-One Container

Indications for Use:

The All-In-One Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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